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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,545	08/29/2001	Lloyd Wolfinbarger JR.	067949-5006-03	5273

9629 7590 02/05/2009

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
02/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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12/08/2008	PAPER

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This office action has been remailed with form 1449 pursuant to the petition of 2/3/09.

Heng Yuen, SPRE
TC3700
2/5/09

Office Action Summary	Application No.	Applicant(s)	
	09/940,545	WOLFINBARGER ET AL.	
	Examiner	Art Unit	
	DAVID COMSTOCK	3733	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment filed 25 July 2008, specifically excluding glucose as the claimed agent, has been fully considered. This negative limitation is deemed to be proper based on the express recitation of glucose and other agents in the specification and in light of *In re Johnson and Farnham*, 194 USPQ 187, 196 (CCPA 1977), which was cited by Applicant. Moreover, the amended claims overcome the outstanding rejection because glucose is the only agent expressly recited in Boyce that appears to satisfy the claimed limitations regarding the agent. However, a newly discovered reference to Myers et al. (3,458,397) renders the claims obvious over the disclosure of Prewett et al. (5,298,254; of record). A rejection based on these references is set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prewett et al. (5,298,254; of record) in view of Myers et al. (3,458,397).

Prewett et al. discloses contacting monolithic bone (see, e.g., Figs. 1-4 and col. 2, lines 45-59) with at least one mechanical strength-conserving liquid organic agent

(see, e.g., col. 4, line 10 - col. 5, line 12). Many of the agents listed by Prewett et al. are identical to those listed by Applicant, including, for example, glycerol, propylene glycol, ethylene glycol, triethylene glycol, sorbitol, mannitol, adonitol, galactose, sucrose, etc. (*cf.*, e.g., Applicant's specification lines 13-15 vis-à-vis col. 4, line 10 - col. 5, line 12 of Prewett et al.). Accordingly, these agents are deemed to have the same characteristics and capabilities as those described by Applicant. Prewett et al. disclose the claimed invention except for lyophilization of the treated bone and packaging thereof. Myers et al. disclose lyophilizing and packaging bone that has been treated with a liquid organic agent such as ethylene glycol, which is one of the agents listed by Applicant (see Myers et al., e.g., col. 1, lines 15-23 and col. 2, line 36 - col. 3, line 3). The freeze drying and packaging into a vial preserves sterility and allows the material to be used at a later time (id., esp. col. 2, line 71 - col. 3, line 3). While the bone of Myers et al. is ground, the reference is still relevant, since it teaches lyophilization and packaging of the combination of bone material and an agent such as ethylene glycol. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have freeze-dried and packaged the bone and agent of Prewett et al., in view of Myers et al., in order to preserve the sterility of the treated bone and to allow it to be used at a later time.

Response to Arguments

While this action presents new grounds of rejection to which Applicant has not yet responded, the following is noted both to facilitate prosecution and to answer remarks previously made by Applicant regarding the Prewett et al. reference, which are relevant to this rejection.

Regarding the term "monolithic," and as already set forth in the rejection, Prewett et al. explicitly disclose monolithic bone, i.e. bone which is cut into the form of a solid structure as opposed to chips or powder (see Prewett et al., e.g., Figs. 1-4 and col. 2, lines 45-59).

In response to Applicant's previous argument pertaining to Prewett et al. (see Remarks by Applicant, page 1, lines 10-22, filed 24 October 2003) that the reference fails to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., "structure that consists of both an inorganic phase and an organic phase") are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The term bone has been construed according to a broadest reasonable interpretation thereof, consistent with the specification. Such interpretation should include any material that is bone, regardless of how it may have been processed or treated. The specification lacks a specific definition of bone, per se, but explicitly defines "bone graft" on page 10. This definition describes the source of the bone but does not in any way preclude demineralized bone. Therefore, while other areas of the specification may describe non-demineralized bone, no such special definition has been

set forth where it would be expected, namely, in the list of special terms and definitions found on pages 9-14 of Applicant's specification. Applicant is reminded that the specification must clearly set forth definitions explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01. Therefore, as Applicant is free to explicitly set forth in the claims that the bone is non-demineralized, and since no special definition of bone that precludes demineralized bone has been set forth in the specification, the term bone is construed to refer to any bone material.

Conclusion

Applicant's amendment, which specifically excludes glucose as the claimed agent, necessitated the new ground(s) of rejection presented in this Office action. Specifically, Applicant added the following clause to each of the only two pending claims, 33 and 34: "wherein said agent is not glucose." Since glucose was not excluded prior to the amendment, and the rejection depended on glucose as an agent, the amendment necessitated the new ground of rejection. Accordingly, pursuant to MPEP 706.07(a), **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

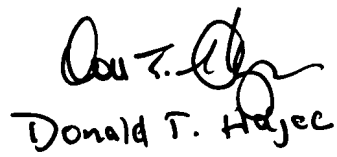
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733



Donald T. Hajec
Director TC 3700